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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,912	01/07/2002	Denis Hunt	H0011/7000	4084

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EXAMINER

LUDLOW, JAN M

ART UNIT PAPER NUMBER

1743

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/041,912	<b>Applicant(s)</b> HUNT ET AL.	
	<b>Examiner</b> Jan M. Ludlow	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 12 September 2005.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1,3-18 and 30-34 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1,3-18 and 30-34 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 15 April 2002 is/are: a)  accepted or b)  objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some \*    c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/22/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

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1. Claims 1, 3-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear how the discreet column insert is “securable to the purification device” when it is part of the purification device, not something separate—does applicant mean “securable to the sample chamber”? In claim 3, “sample holder portion” and “the column insert portion” lack clear antecedence. In claim 3, line 4, should “holder” be “chamber” ? In claim 4, is “a column module” the same or different form “a discreet column insert module” of claim 1? Note that the specification refers to the cylindrical portion of the sample holder that receives the column module as “column insert portion” whereas applicant is now using the term “column insert module” in claim 1 to refer to the column module (this interpretation is based on the limitation that the column insert module is configured to contain a separation bed in claim 1). It is suggested that applicant review the specification and claims to clarify the language by uniform usage. See also claims 5-6, 10-12, which also recite “the column module”. In claim 4, “the column insert portion” lacks clear antecedence. In claim 7, “opening” should be “outlet” and it is unclear whether “column insert portion and column insert” both refer to the “column insert module” of claim 1 or to something else. Claim 18 depends from cancelled claim 17.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3-5, 7, 10-11, 13, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn (5918273).

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Horn teaches a sample chamber 19 having a greater diameter than cylindrical column insert portion 35 joined by tapered portion 39. Column module 13 may be packed with a chromatography medium, such as derivatized silica having affinity for lipophilic proteins (col. 5, lines 1-15). See, e.g., Fig. 3F. With respect to claim 7, it is the examiner's position that the frit inherently acts to regulate flow. With respect to claim 10, see Fig. 11, where the upper portion of 130 is the sample chamber, the lower portion of 130 is the column insert, and fitting 131 is the removable top portion of module 13. With respect to claim 11, when a user uses a particular column, such as derivatized silica having affinity for lipophilic proteins, the user has inherently selected the packing. With respect to claims 13, 17, 18, see Figures 3A-3B and 4, col. 12, lines 55-60. The column insert has conical sleeve portions at the top and bottom.

7. Claims 6- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn as applied to claims above, and further in view of Shukla (6103195).

8. Horn fails to teach membranes to control flow.

9. Shukla teaches that membranes of different molecular weight cut offs (MWCO), such as UF membranes, can be used in addition to frits in columns to regulate flow rates and provide further separation (abstract, col. 3, lines 3-6, 25-35).

10. It would have been obvious to use the claimed membranes in addition to the frit of Horn in order to provide further separation and/or control flow as taught by Shukla. It would have been obvious to use a microporous membrane in order to vary the MWCO as taught by Shukla.

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11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horn as applied to claims above, and further in view of Applicant's admitted prior art (AAPA).

Horn fails to teach stacked membranes.

AAPA teaches that stacked membranes are conventionally used in place of chromatographic packing (instant disclosure, page 4, lines 6-9).

It would have been obvious to provide stacked membranes in place of the packing of Horn in order to provide a known conventional alternative separation medium as taught by AAPA.

12. Claims 14-16, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horn as applied to claims above and further in view of Franciskovich (5603899).

The teachings of Horn are given above. Horn teaches that fluid can be drawn through the columns by vacuum (col. 9, line 5). Horn further teaches that the columns can be used for chromatography (col. 6, lines 10-23). Buffers can be provided (e.g., col. 11, lines 35-43).

Horn fails to teach a receiving plate with vessels, a barrier, the claimed buffers or different column contents.

Franciskovich teaches a system similar to that of Horn. The columns may have the same or different packings, including affinity packings (col. 4, lines 1-2, lines 53-59), and the columns may be operated by a vacuum manifold including a receiving tray 44 and seal 15.

It would have been obvious to use the columns of Horn with a receiving plate, gasket and manifold in order to provide a known alternative vacuum receiver as taught

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by Franciskovich. It would have been obvious to use different column packings to perform different separations as taught by Franciskovich. It would have been obvious to provide the claimed buffers in order to provide known buffers for the use of the columns as chromatography columns as taught by Horn.

13. Applicant's arguments filed September 12, 2005 have been fully considered but they are not persuasive.

14. The rejection of claim 34 under 35 USC 112, first paragraph, is withdrawn in view of applicant's argument and the fact that applicant is not arguing that patentability rests upon this feature.

15. Applicant argues that Horn does not teach a cylindrical capsule, but the outer wall of Horn is a cylinder as defined by applicant, e.g., has a cylindrical outer **surface**, as in applicant's definition. Further, the instant claims do not preclude a flange, such as element 49 of Horn, integrally connected to the capsule. The interior tapered surfaces 41, 57 inside the outer cylinder of Horn are likewise not precluded by the instant claims. In fact, the instant invention has an interior structure 52 at the bottom of the module which would be precluded by applicant's argument—in other words, the claim is not limited to, e.g., "inner and outer cylindrical wall surfaces extending from a first end wall to a second end wall, the spacing between the wall surfaces being constant between the first and second end walls" and cannot be so limited because the inner wall surface of the instant module changes diameter at feature 52 as shown in Figure 2 of the instant application. In simple terms, applicant teaches an integral lower inner flange, whereas Horn teaches tapered inner surfaces and an integral lower external flange. If applicant

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is arguing that “cylindrical” precludes the tapers and/or flange of Horn, how does applicant account for applicant’s own flange, which narrows the inner diameter of the cylinder at the bottom end?

Applicant argues that Horn does not teach a capsule because it is not capped, but no caps are found in the instant claims, and the instant “capsule” is not capped either—See, e.g., Figure 6, which shows retaining frits like those of Horn (element 65 and the same structure shown at the top of the column). Webster’s Ninth New Collegiate Dictionary defines a capsule as “a compact often sealed and detachable container or compartment” and the column of Horn meets this definition.

Applicant argues that the tapered inner openings of Horn are required for use at high pressures, but the tapered openings are not precluded in the instant claims, and no limitations to pressure are found in the instant claims.

16. Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

Jml  
November 23, 2005